[7590-01-P]

NUCLEAR REGULATORY COMMISSION

[Docket No. 50-608; NRC-2021-0140]

SHINE Medical Technologies, LLC; SHINE Medical Isotope Production Facility

AGENCY: Nuclear Regulatory Commission.

ACTION: Environmental assessment and finding of no significant impact; issuance.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is issuing an environmental assessment (EA) and finding of no significant impact (FONSI) regarding the SHINE Medical Technologies, LLC (SHINE, the licensee) request to amend Construction Permit No. CPMIF-001 for the SHINE Medical Isotope Production Facility (SHINE facility) in Rock County, Wisconsin. The amendment request seeks, in part, NRC approval to extend the latest date for completion of the construction of the SHINE facility from December 31, 2022, to December 31, 2025.

DATES: The EA and FONSI referenced in this document are available on **[INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

ADDRESSES: Please refer to Docket ID **NRC-2021-0140** when contacting the NRC about the availability of information regarding this document. You may obtain publicly available information related to this document using any of the following methods:

- **Federal Rulemaking Website:** Go to https://www.regulations.gov and search for Docket ID **NRC-2021-0140**. Address questions about Docket IDs in Regulations.gov to Stacy Schumann; telephone: 301-415-0624; email: Stacy.Schumann@nrc.gov. For technical questions, contact the individual listed in the "For Further Information Contact" section of this document.

- **NRC's Agencywide Documents Access and Management System (ADAMS):** You may obtain publicly available documents online in the ADAMS Public Documents collection at https://www.nrc.gov/reading-rm/adams.html. To begin the search, select "Begin Web-based ADAMS Search." For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1-800-397-4209,

301-415-4737, or by email to PDR.Resource@nrc.gov. For the convenience of the reader, instructions about obtaining materials referenced in this document are provided in the "Availability of Documents" section.

- **NRC's PDR:** You may examine and order copies of public documents, by appointment, at the NRC's PDR, Room P1 B35, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852. To make an appointment to visit the PDR, please send an email to PDR.Resource@nrc.gov or call 1-800-397-4209 or 301-415-4737, between 8:00 a.m. and 4:00 p.m. Eastern Time (ET), Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Michael Balazik, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington DC 20555-0001; telephone: 301-415-2856; email: Michael.Balazik@nrc.gov.

SUPPLEMENTARY INFORMATION:

I. Introduction

The NRC is considering issuance of an amendment to Construction Permit No. CPMIF-001, issued to SHINE for the construction of the SHINE facility in Rock County, Wisconsin. SHINE requested the amendment by letter dated April 1, 2022, in accordance with section 50.90 of title 10 of the *Code of Federal Regulations* (10 CFR), "Application for amendment of license, construction permit, or early site permit," and 10 CFR 50.33, "Contents of applications; general information." The amendment would extend the latest date for completion of the construction of the SHINE facility from December 31, 2022, to December 31, 2025.

In accordance with 10 CFR 51.21, "Criteria for and identification of licensing and regulatory actions requiring environmental assessments," the NRC prepared an EA, pursuant to 10 CFR 51.30, "Environmental assessment," that analyzes the environmental impacts of the proposed amendment and alternatives as appropriate. Based on the results of this EA, which is set forth in Section II in this document, and in accordance with 10 CFR 51.31(a), the NRC has determined not to prepare an

environmental impact statement for the proposed amendment and is issuing a FONSI, which is set forth in Section III in this document.

II. Environmental Assessment

Description of the Proposed Action

The proposed action would amend Construction Permit No. CPMIF-001 to extend the latest date for completion of the construction of the SHINE facility from December 31, 2022, to December 31, 2025. The proposed action is requested in the licensee's application dated April 1, 2022.

The proposed action would not allow any work to be performed that is not already authorized by the construction permit. The proposed action would grant SHINE more time to complete the construction of the SHINE facility in accordance with the construction permit.

Need for the Proposed Action

SHINE completed a review of the construction schedule for the SHINE facility and determined that construction will not be completed by December 31, 2022, the latest date for completion of the construction of the SHINE facility prescribed by the construction permit. SHINE stated that developmental effort delays have occurred due to the first-of-a-kind nature of the SHINE facility. Furthermore, the COVID-19 public health emergency slowed efforts related to obtaining the workforce and equipment resources needed to procure and install the necessary process equipment to complete facility construction. SHINE now expects the construction of the SHINE facility to be substantially completed in May 2023 and the remaining uncompleted items of construction completed by August 2025. To accommodate this construction schedule and to incorporate conservatism, SHINE is requesting to extend the latest date for completion of the construction of the SHINE facility to December 31, 2025.

The NRC regulation in 10 CFR 50.55(b) states that upon good cause shown, the Commission will extend the completion date for a reasonable period of time and that the Commission will recognize, among other things, "developmental problems attributable to

the experimental nature of the facility or fire, flood, explosion, strike, sabotage, domestic violence, enemy action, an act of the elements, and other acts beyond the control of the permit holder," as a basis for extending the completion date.

Environmental Impacts of the Proposed Action

The NRC has completed its environmental review of the proposed action and concludes that there are no significant environmental impacts associated with the proposed action.

The proposed action would only extend the period of construction activities already authorized by the construction permit and would not authorize any new construction activities, any additional land disturbance, or any modifications to the facility from the terms in the construction permit.

In 2015, the NRC evaluated the environmental impacts associated with constructing, operating, and decommissioning the SHINE facility in NUREG-2183, ''Environmental Impact Statement for the Construction Permit for the SHINE Medical Radioisotope Production Facility.'' NUREG-2183 concluded that the environmental impacts associated with the construction of the SHINE facility would be SMALL for all resource areas with the exception of traffic, which would incur MODERATE impacts. In 2022, the NRC issued NUREG-2183, Supplement 1, "Environmental Impact Statement Related to the Operating License for the SHINE Medical Isotope Production Facility: Draft Report for Comment," which updates NUREG-2183 and only covers matters that differ from those or that reflect significant new information relative to that discussed in NUREG-2183. NUREG-2183, Supplement 1 considered any different information since NUREG-2183 and concluded that there is no significant new information with respect to the environmental impacts of the SHINE facility.

In May 2019, SHINE commenced site-preparation work and NRC-authorized construction of the exterior of the SHINE facility. SHINE completed the construction of the main production facility building in March 2021. Therefore, most of the construction impacts discussed in NUREG-2183 and NUREG-2183, Supplement 1 have already

occurred. The proposed action would not result in additional worker vehicles, additional truck deliveries, new land disturbance, new construction, or modification of the SHINE facility from what was previously assessed in NUREG-2183 and NUREG-2183, Supplement 1. No changes to the facility's Wisconsin Pollutant Discharge Elimination System permit are needed. There would be no changes to the types or quantity of non-radiological effluents previously assessed in NUREG-2183 and NUREG-2183, Supplement 1. The proposed action would not represent a change in the types or quantity of radioactive materials in effluents, wastes, and products of the SHINE facility. SHINE continues to be required to comply with occupational dose limits for adults (10 CFR Part 20, Subpart C) and radiation dose limits for individual members of the public (10 CFR Part 20, Subpart D) at all times. The proposed action would not have a significant adverse effect on the probability of an accident occurring. Since the proposed action would only extend the period of already authorized construction activities, it does not involve any different impacts or significant changes to those impacts described and analyzed in the previous environmental documents. Therefore, there would be no significant non-radiological or radiological environmental impacts associated with the proposed action.

Environmental Impacts of the Alternatives to the Proposed Action

As an alternative to the proposed action, the NRC staff considered denial of the proposed action (i.e., the "no-action" alternative). Denial of the amendment request would result in the licensee being unable to complete construction and begin operation of the SHINE facility. However, because the direct impacts on land use and water resources from construction have largely already occurred and because the remaining construction, operating, and decommissioning impacts would generally be small as evaluated in NUREG-2183 and NUREG-2183, Supplement 1, the environmental impacts of the proposed action and the alternative action are similar.

Alternative Use of Resources

There are no unresolved conflicts concerning alternative uses of available

resources under the proposed action. The proposed action does not involve the use of any resources not previously considered in NUREG-2183 and NUREG-2183, Supplement 1.

Agencies and Persons Consulted

No additional agencies or persons were consulted regarding the environmental impact of the proposed action. On October 11, 2022, the NRC notified the Wisconsin Department of Health Services of the EA and FONSI. The state provided no comments. The NRC staff determined that the proposed action would have no effect on Federally listed threatened or endangered species or critical habitat that could occur on or near the SHINE facility site and would have no effect on any historic properties. Therefore, consultation was not required under section 7 of the Endangered Species Act of 1973, as amended, or under section 106 of the National Historic Preservation Act of 1966, as amended.

III. Finding of No Significant Impact

The proposed action is the issuance of an amendment to SHINE Construction Permit No. CPMIF-001 to extend the latest date for completion of the construction of the SHINE facility from December 31, 2022, to December 31, 2025. Consistent with 10 CFR 51.21, the NRC prepared an EA to determine the impacts of the proposed action. On the basis of the EA included in Section II in this document and incorporated by reference in this finding, the NRC concludes that the proposed action would not have a significant adverse effect on the probability of an accident occurring and would not have any significant radiological or non-radiological impacts. Therefore, the NRC concludes that the proposed action will not have a significant effect on the quality of the human environment. Accordingly, the NRC has determined not to prepare an environmental impact statement for the proposed action.

Other than the application dated April 1, 2022, the related environmental documents are NUREG-2183, “Environmental Impact Statement for the Construction Permit for the SHINE Medical Radioisotope Production Facility,” and NUREG-2183,

Supplement 1, “Environmental Impact Statement Related to the Operating License for the SHINE Medical Isotope Production Facility: Draft Report for Comment,” which provide the latest environmental review of the construction, operation, and decommissioning of the SHINE facility and description of the environmental conditions at the SHINE facility site.

This EA and FONSI and other related documents are accessible online in the ADAMS Public Documents collection at https://www.nrc.gov/reading-rm/adams.html. Persons who do not have access to ADAMS or who encounter problems in accessing the documents located in ADAMS should contact the NRC’s PDR reference staff at 1-800-397-4209 or 301-415-4737, or by email to PDR.Resource@nrc.gov.

IV. Availability of Documents

The documents identified in the following table are available to interested persons through ADAMS, as indicated.

DOCUMENT	ADAMS ACCESSION NO.
NUREG-2183, “Environmental Impact Statement for the Construction Permit for the SHINE Medical Radioisotope Production Facility,” dated October 2015	ML15288A046
NUREG-2183, Supplement 1, “Environmental Impact Statement Related to the Operating License for the SHINE Medical Isotope Production Facility: Draft Report for Comment,” dated June 2022	ML22179A346
Construction Permit No. CPMIF-001 for the SHINE Medical Isotope Production Facility, dated February 29, 2016	ML16041A471
SHINE Medical Technologies, LLC, “Request to Amend Construction Permit No. CPMIF-001,” dated April 1, 2022	ML22091A093

Dated: November 4, 2022.

For the Nuclear Regulatory Commission.

Joshua M. Borromeo,
Chief, Non-Power Production and Utilization Facility Licensing Branch,
Division of Advanced Reactors and Non-Power Production and Utilization Facilities,
Office of Nuclear Reactor Regulation.

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